

WHOLESALE DISTRIBUTOR APPLICATION INSTRUCTIONS

- Complete the attached Maryland Board of Pharmacy's **Application for Wholesale Distributor Permit**. Be sure to check the box for the relevant application type (New, Renewal, Ownership Change, Relocation, or Reinstatement).

NOTE: The Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act (Md. Code Ann., Health Occ. § 12-6C-01 *et seq.*) requires a wholesale distributor to hold a permit issued by the Board before engaging in wholesale distribution of prescription drugs or devices into or within the State. For further details, please review the Act and the relevant Board regulations located in COMAR 10.34.22.01 – 08.

- Submit the completed application with all attachments and a check made payable to the Maryland Board of Pharmacy in the appropriate amount to: Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215.
- The application process must be completed within one year from submission of the initial application. Applicants failing to complete the process within one year will be required to submit a new application.
- A completed application must include:
 - Physical property documentation;
 - A copy of the facility-specific surety bond or irrevocable letter of credit;
 - Evidence of general and product liability insurance;
 - A copy of the inspection or accreditation report;
 - Evidence of DEA and Maryland CDS registration, if applicable;
 - A list of all federal and state licenses, registrations, and/or permits;
 - A list of all disciplinary actions taken by federal and/or state agencies against the wholesale distributor and/or any principals, owners, directors, or officers;
 - For the designated representative and the immediate supervisor of the designated representative:
 - A photograph taken in the previous 180 days;
 - A resume; and
 - Results of a federal criminal background check and a criminal background check from the individual's state of residence;
 - The appropriate application fee (\$1,750 for New, Renewal, Ownership Change, or Relocation applications; \$3,250 for Reinstatement applications); and
 - Any other documentation required in COMAR 10.34.22.03.

NOTE: Proof of a single surety bond of \$100,000 or \$50,000 must be submitted and shall cover all facilities located in the State of Maryland operated by the applicant. Applicants submitting a \$50,000 surety bond must submit proof that the applicants' annual gross receipts in the State of Maryland for the tax previous year are less than \$10,000,000. For further details on surety bonds, please review Md. Code Ann., Health Occ. § 12-6C-05(f) and COMAR 10.34.22.03.E.

- For **IN-STATE APPLICANTS**, the Board may not issue a wholesale distributor permit unless the Board or its designee conducts a physical inspection of the applicant's place of business, including any facility owned or operated by the applicant.

- For **OUT-OF-STATE APPLICANTS**, the Board may not issue a wholesale distributor permit unless the applicant is accredited by a Board-recognized accrediting program or eligible for reciprocity. **Board-recognized accrediting programs include:**
 - **For Wholesale Distributors who hold product:** The National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD) program;
 - **For Wholesale Distributors of oxygen:** The American Commission for Health Care, Inc. (ACHC); and
 - **For Whole Distributors of medical gases other than oxygen:** The Community Health Accreditation Program (CHAP)
- Out-of-state applicants for a wholesale distributor permit may be eligible for reciprocity if they are located in a state with requirements that are substantially equivalent to Maryland's wholesale distributor requirements, including requirements for pedigree, routine inspections, and security measures, and a prohibition against operating in a residence. Reciprocal applicants must submit a copy of an inspection report issued by an agency in the state of residence completed within the previous two years, but they need not be accredited. **Current reciprocal states include Arizona; California (devices only); Colorado; Florida; Georgia; Idaho; Illinois; Indiana; Kentucky; Nebraska; Nevada; Oklahoma (human drugs only); Oregon; and Wyoming.**

NOTE: An out-of-state wholesale distributor applicant's state of residence must enforce all relevant requirements in order for the applicant to qualify for reciprocity.

NOTE: Please allow four to six weeks for the Board to process your completed application.

NOTE: The application fee is a non-refundable, administrative fee.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore MD 21215-2299
Phone: 410-764-4759
Fax: 410-358-6207
www.dhmfh.maryland.gov/pharmacy



APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

BOARD USE ONLY

Permit Number: _____ Approval Date: _____ Approval By: _____

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

Application Type:

☐ New ☐ Renewal ☐ Ownership Change ☐ Renewal
(\$1,750.00 application fee)

☐ Reinstatement
(\$3,250.00 application fee)

1. APPLICANT INFORMATION

A. _____
Name of Applicant (*name in which company is doing business*) Permit Number (*if applicable*)

B. Facility Address (*physical location of establishment which should be reflected on all sales invoices and shipping documents*):

Street Address	Suite No.	
City	State	Zip Code
Telephone Number	Fax Number	
Website	Email Address	Federal Tax Id No.

C. Type of business (*check all that apply*):

☐ Sole Proprietorship ☐ Partnership ☐ C Corporation
☐ S Corporation ☐ LLC ☐ Other (*please explain*)

D. Legal Name: _____ State of Incorporation/Date: _____ / _____
(*If different from Applicant Name*)

E. Parent Companies (*include any and all companies that have direct or indirect control over the applicant*)

F. Resident Agent (*attach Resident Agent Agreement, if applicable*):

Name	Title	
Street Address	Suite No.	
City	State	Zip Code
Telephone Number	Fax Number	

2. FACILITY INFORMATION

A. Date of last inspection by a state agency, accreditation program, or FDA: _____
(*attach most recent inspection report*)

B. Accreditation program (*attach proof of accreditation, if applicable*):

- | | |
|-------------------------------|---|
| <input type="checkbox"/> VAWD | <input type="checkbox"/> ACHC |
| <input type="checkbox"/> CHAP | <input type="checkbox"/> Joint Commission |

C. DEA Registration # _____ Maryland CDS Registration # _____
(*attach copies of registration certificates*)

D. State and Federal permit/license/registration numbers (*non-resident applicants – include a copy of the permit/license/registration in your state of residence*) (*attach additional pages if necessary*):

Licensing Body	Permit/License/Registration Number
_____	_____
_____	_____
_____	_____

E. Facility ownership description (*attach copy of lease or deed*):

- ☐ Own ☐ Rent

1. Number of years in current facility: _____

2. Name of lessor (*if applicable*): _____

F. Facility physical description (*see COMAR 10.34.22.03 and .06*)

1. Square footage: _____

2. Description of security and alarm systems:

3. Description of temperature and humidity control monitoring:

3. OPERATIONS

A. Hours of operation:

Sunday	_____	Thursday	_____
Monday	_____	Friday	_____
Tuesday	_____	Saturday	_____
Wednesday	_____		

B. Products distributed (*check all applicable boxes*) (*please send a list of the products distributed--do not send catalogs*):

<input type="checkbox"/> Drugs	<input type="checkbox"/> Devices
<input type="checkbox"/> Prescription	<input type="checkbox"/> Class I
<input type="checkbox"/> Non-prescription	<input type="checkbox"/> Class II
<input type="checkbox"/> Controlled dangerous substances (CDS)	<input type="checkbox"/> Class III
<input type="checkbox"/> Medical Gasses	

C. Import Activities (*list all countries of import for each facility listed on application*):

If you import CDS, please attach DEA Form 357.

4. OWNERSHIP

Please include the following on a separate sheet:

1. Full name, title, date of birth, and business address for owner, sole proprietor, each partner, and/or each corporate director or officer;
2. Full name, title, date of birth, and business address for each manager of an LLC;
3. Full name, title, date of birth and business address for each shareholders owning 10% or more of the shares for a *non-publicly traded corporation*; and
4. Corporate name for a non-publicly traded corporation;

5. DISCIPLINARY ACTIONS

Please include a separate sheet listing all disciplinary actions by federal or state agencies against the wholesale distributor, as well as any such actions against principals, owners, directors, or officers. Please include documentation of any corrective actions taken in response to any disciplinary actions and any final orders issued by any federal or state agencies. **Renewal, relocation, and reinstatement applicants - please only include information since your last application with the Board.**

6. SURETY BOND

Is a surety bond or other equivalent means of security attached? ☐ Yes ☐ No

☐ Annual gross receipts in Maryland for previous tax year are less than \$10,000,000
(please attach appropriate documentation)

☐ Annual gross receipts in Maryland for previous tax year are \$10,000,000 or more

7. DESIGNATED REPRESENTATIVE/DIRECT SUPERVISOR

Please complete and attach Attachment 1 – Designated Representative and Attachment 2 – Direct Supervisor of Designated Representative.

8. SIGNATURE

By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in a Maryland wholesale distributor permit may be revoked if any assertion made in this application is found to be false.

Signature of Applicant

Business Telephone Number

Business Fax Number

Printed Name and Title

9. APPLICATION CHECKLIST

Application Fee (\$1,750 or \$3,250)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Resident Agent Agreement (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Most Recent Inspection Report	<input type="checkbox"/> YES <input type="checkbox"/> NO
Proof of Accreditation (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Copies of DEA & Maryland CDS Registration Certificates	<input type="checkbox"/> YES <input type="checkbox"/> NO
Copy of Permit from State of Residence (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Copy of Lease or Deed	<input type="checkbox"/> YES <input type="checkbox"/> NO
DEA Form 357 (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Ownership Information	<input type="checkbox"/> YES <input type="checkbox"/> NO
Surety Bond (or other similar security)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Proof of Annual Gross Receipts (if applicable)	<input type="checkbox"/> YES <input type="checkbox"/> NO
Evidence of General/Product Liability Insurance	<input type="checkbox"/> YES <input type="checkbox"/> NO
Attachment 1 – Designated Representative	<input type="checkbox"/> YES <input type="checkbox"/> NO
Attachment 2 – Immediate Supervisor of Designated Rep.	<input type="checkbox"/> YES <input type="checkbox"/> NO

APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

ATTACHMENT 1

DESIGNATED REPRESENTATIVE

Place a recent photograph in this space

Attach a photograph showing your face, with a three quarter view. The photograph **must be recent and in good condition.**

- Please print clearly in ink or type in upper case letters only.
- Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

I certify that this is a photograph of me taken within the previous 180 days of submitting this application.

(Sign Here)

1. IDENTIFICATION

First Name	Middle/Maiden Name	Last Name	Date and Place of Birth	
Street Address		City	State	Zip
Work Phone () - Ext.		Email Address		

2. PLACES OF RESIDENCE: Complete the following table with your places of residence for the previous seven (7) years.

Date(s)	Address	City, State, Zip

3. EMPLOYMENT INFORMATION: Complete the following table with your places of employment for the previous seven (7) years.

Employer Name	Job Title	Date of Hire	Date of Termination	Address	City, State, Zip

4. PERSONAL ATTESTATION QUESTIONS

Initial each statement to indicate your understanding and agreement to abide by the requirements of a designated representative for a wholesale distributor:

- _____ Employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping related to prescription drugs.
- _____ Employed by the applicant full time in a managerial level position.
- _____ Actively involved in, and aware of, the daily operation of the wholesale distributor.
- _____ Physically present, except for an authorized absence such as sick or vacation leave, at the facility of the applicant during regular business hours.
- _____ Serving as a designated representative for only one applicant at a time, or for two or more members of an affiliated group as defined in §1504 of the Internal Revenue Code.
- _____ Does not have any convictions for a violation of any federal, state or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances.
- _____ Does not have any convictions for a felony under federal, state, or local laws.

5. ADDITIONAL QUESTIONS

If you answer "yes" to any question, please provide a detailed explanation (attach additional pages if necessary) and supporting documentation. Failure to provide complete and correct information may result in delay, or denial, of your wholesale distributor application.

Have you been involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you been involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund) that has been named a party in a lawsuit?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you been the subject of any proceeding for the revocation of any professional or business license or any criminal violation? If yes, provide the details of the nature and disposition of the proceeding.	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs? If yes, provide the details and any documentation regarding the event.	<input type="checkbox"/> YES <input type="checkbox"/> NO
Have you been found guilty of any misdemeanor or felony offense (regardless of whether adjudication of the guilt was withheld, you pled guilty or <i>nolo contendere</i> ** or whether the criminal conviction is under appeal) as an adult?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have a criminal conviction currently under appeal at the time of this application? If yes, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal) should accompany this application.	<input type="checkbox"/> YES <input type="checkbox"/> NO

**** *Nolo contendere*- A plea in a criminal case which has a similar legal effect as pleading guilty. The defendant does not admit or deny the charges, but a fine or sentence may be imposed based on this plea****

SIGNATURE: Designated Representative

By signing this application, I solemnly affirm under the penalties of perjury that the contents of this section (Section VII) of the application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of a Designated Representative under the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in the Maryland wholesale distributor permit issued pursuant to this application may be revoked if any assertion made in this application is found to be false.

Name - Typed

Date of birth and place of birth (Must be 21 y/o or older)

Telephone

Fax

Signature

Date

6. CRIMINAL BACKGROUND CHECK

Initial each line and attach information with the application.

_____ 1. Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigations;

_____ 2. Regarding the background checks, Maryland law changed in 2012 and now requires the Designated Representative and Supervisor of the Designated Representative to have the background check, both State and Federal completed in the state of residence.

There have been issues with obtaining the federal background check in other states, specifically; the MD ORI # is not acceptable outside of Maryland.

There are currently two options regarding the Federal background check.

- Have the state check completed in the State of residence also submit background cards for the State and Federal level checks to the State of Maryland for processing (the federal check cannot be completed without the state check)

- Submit the federal background check directly to the FBI also submit a request to the Maryland Board of Pharmacy for an extension pending the receipt of the federal background results (<http://www.fbi.gov/about-us/cjis/background-checks>)

APPLICATION FOR WHOLESALE DISTRIBUTOR PERMIT

ATTACHMENT 2

IMMEDIATE SUPERVISOR OF DESIGNATED REPRESENTATIVE

Place a recent photograph in this space

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Have you been involved with or have any investments in any business(es) that manufactures, administers, prescribes, distributes or stores prescription drugs (other than the ownership of stock in a publicly traded company or mutual fund)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
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Have you been the subject of any proceeding for the revocation of any professional or business license or any criminal violation? If yes, provide the details of the nature and disposition of the proceeding.	<input type="checkbox"/> YES <input type="checkbox"/> NO
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Have you been found guilty of any misdemeanor or felony offense (regardless of whether adjudication of the guilt was withheld, you pled guilty or <i>nolo contendere</i> ** or whether the criminal conviction is under appeal) as an adult?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have a criminal conviction currently under appeal at the time of this application? If yes, a copy of the notice of appeal (a final written order of disposition must be submitted within 15 days after the disposition of the appeal) should accompany this application.	<input type="checkbox"/> YES <input type="checkbox"/> NO

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SIGNATURE: Immediate Supervisor of the Designated Representative

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